69. (New) The method of claim 22 where the fingerprint spectra are pyrolysis mass spectra.

a1 70. (New) The method of claim 20, further comprising adding the expected spectrum of the microorganism of interest to a database.--

Remarks

1. Summary of Examiner's Interview

On March 26, 2003, a telephone interview of Examiner Ly and his supervisor, Examiner Marschel, was conducted by attorneys for the applicant. During this interview, Examiners Ly and Marschel were asked to clarify the basis of the restriction requirements, especially in view of their classification of several Groups of claims into the same class and subclass. The Examiners explained that, in addition to the basis provided in the written Restriction Requirement (i.e. differences in the preamble language), there were differences in the specific steps recited by the various Groups of claims that allegedly require different search strategies. Applicants thank the Examiners for their time and for clarifying the basis for the restriction requirements.

The Examiners were also asked to clarify the requested species election, particularly with respect to election of a single species of microorganism. The Examiners explained that upon allowance of a generic claim, applicants would be entitled to consideration of claims to additional species. Applicants thank the Examiners for clarification of the requested species election.

2. Status of the Application

Pending claims 1-66 are subject to restriction and species election requirements. The Office action alleges that the claims, as grouped into Groups I-VII, are directed to distinct inventions because they are directed to different methods regarding the critical limitations and active steps therein. The Office action also alleges that claims are directed to three types of patently distinct species: environmental condition parameters, fingerprint spectra and species of microorganism. The Office action alleges that a search of all claim groups and species would present an undue burden on the Examiner. Applicants respectfully disagree.

3. Support for New Claims 67-70

Support for new claim 67 may be found, for example, on page 18, lines 18-26 where the application states that "the disclosed methods are based upon the discovery that it is possible to correct drift (instrumental and environmental) in the fingerprint spectra of a plurality of metabolically similar microorganisms with reference to fingerprint spectra of a single microorganism within that plurality of metabolically similar microorganisms." Also at this location, environmental drift is disclosed to include, for example, a change in growth medium. Examples 2 (pages 29-32) and 4 (pages 35-47) are detailed examples discussing the use of the disclosed methods to compensate for changes in growth media.

Support for new claim 68 may be found, for example, from page 24, line 14 to page 25, line 8. Here, the application discusses how to compensate for differences between batches of the same growth medium. In particular, it discusses how differences between the fingerprint spectra of a metabolically similar microorganism grown on a new library database growth medium and an exhausted library database medium may be used to correct for drift of a microorganism of interest between the two library database media.

Support for new claim 69 may be found, for example, on page 35, lines 6-29.

Support for new claim 70 may be found, for example, from page 21, line 15 to page 25, line 19. Here, the application describes how the methods of compensating for drift in fingerprint spectra may be used to assemble a database. In particular, from page 24, lines 14 to page 25, line 8, an example of how the methods for compensating for a change in growth medium may be used to add fingerprint spectra of microorganisms to a database is presented.

4. Restriction

Applicants elect Group II for prosecution, with traverse, and request that the claims in Groups III and IV be rejoined with the claims of Group II. In the written Restriction Requirement, the claim groupings were supported specifically by the preamble language of the claims. Applicants submit that by failing to fully explain how the critical limitations and the active steps in the claims support restriction, the written Restriction Requirement does not establish a *prima facie* case in support of the restriction. Applicants are grateful for the Examiners' clarification of the basis for the Restriction Requirement, and it is on the basis of those clarifications that this response is made.

a. Groups II and III

Group III should be rejoined with Group II because the claims in these two groups do not differ to an extent that makes their simultaneous examination an undue burden for the Examiner. For example, the claims of both Groups II and III recite culturing, measuring, detecting and using limitations.

The culturing limitations recited in the independent claims of Groups II and III should not form the basis of restriction between Groups II and III. Claim 20, the independent claim of Group II, recites culturing microorganisms under first and second sets of environmental factors. As defined on page 6, lines 21-28, environmental factors are "the chemical and physical parameters that characterize an environment." Environmental factors are disclosed to include constituents of "the substrate (e.g. a microbial growth medium) supporting growth of an organism." Claim 33, the independent claim of group III, is a special case of the method of claim 20 with respect to the culturing limitation. Claim 33 recites culturing microorganisms on a test growth medium and on a library growth medium. By definition, the environmental factors of Group II encompass the growth media of Group III. Furthermore, the language of dependent claim 21 clearly demonstrates that the culturing limitations of Group III are a particular case of the culturing limitations of Group II. Dependent claim 21 of Group II recites, "the method of claim 20 where culturing under a first set of environmental factors comprises culturing on a test growth medium and culturing under the second set of environmental factors comprises culturing on a library growth medium." Thus, restriction between Groups II and III is not supported on the basis of the culturing limitations.

Independent claim 20 of Group II recites measuring fingerprint spectra of a microorganism of interest and a second microorganism that is presumably metabolically similar to the microorganism of interest. Independent claim 33 of Group III recites measuring fingerprint spectra of a microorganism of interest and a second microorganism that is presumably metabolically similar to the microorganism of interest. The independent claims of Groups II and III should not be restricted on the basis of their measuring limitations.

The detecting and using limitations do not support restriction between the claims of Groups II and III. Independent claim 20 of Group II recites "detecting differences between the fingerprint spectr[a] of the second microorganism cultured under the [first and second sets of

environmental factors.]" Independent claim 33 of Group II recites "detecting differences between the fingerprint spectr[a] of the second microorganism cultured on the [test and library growth media.]" Independent claim 20 of Group II recites "using the differences ... to transform the fingerprint spectrum of the microorganism of interest cultured under the first set of environmental factors to an expected fingerprint spectrum for the microorganism of interest under the second set of environmental factors." Independent claim 33 of Group III recites "using the differences ... to transform the fingerprint spectrum of the microorganism of interest to an expected fingerprint spectrum for the microorganism of interest cultured on the library growth medium." As explained above, growth media of Group III are a particular case of the sets of environmental factors of Group II. Thus, the detecting and using limitations of the independent claims of Groups II and III do not justify restriction between the two groups.

Independent claim 33 of Group III includes an additional limitation of "detecting a similarity between the expected fingerprint [for the microorganism of interest] and a library fingerprint spectrum of a known microorganism." The additional limitation of independent claim 33 of Group III extends the method of independent claim 20 of Group II and does not support restriction between the two groups. Dependent claim 23 of Group II makes this clear. Claim 23 recites "[t]he method of claim 20 including a step of identifying the microorganism of interest by detecting a similarity between the expected fingerprint spectrum of the microorganism of interest and a fingerprint spectrum of a known organism cultured under the second set of environmental factors." Restriction between Groups II and III is not justified on the basis of the "detecting a similarity" limitation, since this limitation appears in both Groups II and III.

Since, as explained above, Groups II and III are similar with respect to their active steps and critical limitations, no undue burden for concurrent examination exists and restriction between should not be required. Furthermore, dependent claim 23 demonstrates that differences in the preamble language of claims 20 (Group II, method of compensating for drift) and 33 (Group III, method for identifying a microorganism of interest) do not justify restriction between Groups II and III. The restriction requirement between Groups II and III should be withdrawn. Applicants request that the restriction requirement between Groups II and III be withdrawn.

b. Groups II and IV

Groups II and IV should be rejoined because the limitations of the independent claims in these two groups also do not differ to an extent that makes their simultaneous examination an undue burden. Independent claim 39 is directed to a method for identifying an unknown microorganism. As explained on page 9, lines 20-22, a microorganism of interest may be "a microorganism for which an identity ... has not been established but for which such information is desired." In other words, the term "microorganism of interest" clearly includes an unknown microorganism. Thus, the microorganism of interest of Claim 20 of Group II, for which compensation of drift in its fingerprint spectrum is desired, may be an unknown microorganism. Claim 39, of group IV, is a particular application of the method of independent claim 20 of Group II. As mentioned before, the language of dependent claim 23 of Group II clearly demonstrates that identification of microorganisms is within the scope of the claims of Group II. Restriction between groups II and IV is not justified on the basis of the differing preamble language.

The active steps and critical limitations found in Groups II and IV do not differ to an extent that justifies restriction between the two groups. Both independent claim 20 of Group II and independent claim 39 of Group IV recite measuring limitations. The measuring limitation of claim 20 of Group II recites measuring fingerprint spectra of a microorganism of interest (which may be an unknown) and a presumably metabolically similar microorganism. The measuring limitation of claim 39 of Group IV recites measuring for an unknown and a presumably metabolically similar microorganism. Restriction between Groups II and IV should not be required.

Although claim 39 does not recite an active step of culturing like claim 20 of Group II, the absence of such a step does not justify restriction between Groups II and IV. Claim 39, recites "measuring a fingerprint spectrum of a microorganism that is presumably metabolically similar to the unknown microorganism and is cultured on a first growth medium" and "measuring a fingerprint spectrum of the microorganism of interest and the presumably metabolically similar microorganism cultured on a second growth medium." Thus, both the claims of Group II and the claims of Group IV include limitations regarding culture of microorganisms. Undue burden for simultaneous examination of Groups II and IV is not supported by a culturing step, and restriction on this basis should not be required.

Claim 39 (Group IV) includes steps of "determining" and "using a transformation algorithm." Determining and using a transformation algorithm represents a particular case of "detecting differences" and "using differences to ... transform" as recited in claim 20 of Group II. In fact, on page 14, lines 18-25 the terms "transformation" and "transform" are equated and broadly defined as "application of a relationship between two fingerprint spectra ... in order to convert one fingerprint spectrum to the other." The term also "includes the act of applying a relationship derived between fingerprint spectra of one microorganism to fingerprint spectra of other microorganisms." Determining a transformation algorithm is one method of detecting differences between fingerprint spectra. This assertion is supported by dependent claim 25 (Group II) which recites "[t]he method of claim 20 where using differences ... comprises using proportional differences in individual elements of the fingerprint spectra." Dependent claim 40 (Group IV) recites "[t]he method of claim 39 where determining the transformation algorithm comprises dividing the fingerprint spectrum of the presumably metabolically similar microorganism cultured on the first growth medium by its fingerprint spectrum when cultured on the second growth medium to yield a set of ratios." In other words, the proportional differences (ratios) that may be used in the claims of Group II to "transform" spectra are a "transformation algorithm" as recited in Group IV. Furthermore, in both Groups II and IV, the end result of "using the differences" and "using the transformation algorithm" is identical. In both cases these steps are used to provide an "expected fingerprint spectrum." Restriction between Groups II and IV should not be required.

Based on the reasons above, applicants respectfully submit that no undue burden exists for simultaneous examination of Groups II and IV. Therefore, applicants request that the restriction requirement between Groups II and IV be withdrawn, and that the claims of Groups II and IV be rejoined for prosecution in this application.

c. Groups III and IV

For many of the same reasons give above with respect to restriction between Groups II and III and Groups II and IV, restriction between Groups III and IV should not be required. The differing preamble language of claims 33 and 39 does not justify restriction because claim 33 recites a method for identifying a microorganism of interest and claim 39 recites a method for

identifying an unknown microorganism, which as described above is one type of microorganism of interest.

Although claim 39 does not recite an active step of culturing like claim 33 of Group III, the absence of such a step does not justify restriction between Groups III and IV. Claim 39, recites "measuring a fingerprint spectrum of a microorganism that is presumably metabolically similar to the unknown microorganism and is cultured on a first growth medium" and "measuring a fingerprint spectrum of the microorganism of interest and the presumably metabolically similar microorganism cultured on a second growth medium.". Thus, both the claims of Group III and the claims of Group IV refer to culture of microorganism. An undue burden for examination of both groups is not present and restriction between Groups III and IV based on a culturing step should not be required.

The measuring steps of the independent claims of Groups III and IV do not justify restriction. Measuring fingerprint spectra of microorganisms cultured on test and library growth media (Group III) are a special case of measuring fingerprint spectra of microorganisms cultured on first and second growth media (Group IV). Therefore, restriction between Groups III and IV on the basis of their measuring limitations should not be required.

In addition, and as explained above with respect to Groups II and IV, the steps of detecting differences and using such differences to transform a fingerprint spectrum of a microorganism into an expected fingerprint spectrum (claim 33, Group III) encompass the specific methods of determining and using a transformation algorithm that is recited in independent claim 39 of Group IV. Restriction on this basis should not be requested.

Both sets of claims (III and IV) recite the feature of an expected fingerprint spectrum and use of the expected fingerprint spectrum to identify a microorganism. In independent claim 33 of Group III, similarities are detected between the expected fingerprint spectrum of the microorganism of interest and a library fingerprint spectrum of a known microorganism. In independent claim 39 of Group IV, the expected fingerprint spectrum for the unknown microorganism is compared to fingerprint spectra of known microorganisms cultured on the first growth medium. "Detecting similarities" and "comparing," as recited in claims 33 and 39, are limitations that may be examined together without undue burden and do not support restriction between Groups III and IV.

For all the reasons given above, applicants submit that Groups III and IV should be examined together, and that examination of Groups III and IV simultaneously does not represent an undue burden for the Examiner. Furthermore, since an undue burden is not presented for simultaneous examination of Groups II and III, Groups III and IV, and Groups II and IV, simultaneous examination of Groups II, III and IV does not represent an undue burden. Applicants therefore request modification of the restriction requirements such that Groups II, III and IV are examined together.

4. Species election

Applicants elect the species of temperature as the environmental condition.

Applicants elect the species of pyrolysis mass spectra as the fingerprint spectrum.

Applicants elect the species of *Salmonella* spp. as the microorganism.

Claims 20-32 and new claims 67-70 read on each of the elected species since temperature can be part of the first and second sets of environmental parameters, pyrolysis mass spectra may be the fingerprint spectra, and either the microorganism of interest or the presumably metabolically similar microorganism may be a *Salmonella* spp.

Claims 33-47 read on the species of pyrolysis mass spectra and *Salmonella* spp.

5. Conclusion

Applicants request modification of the restriction requirements so that Groups II, III and IV (as outlined in the Office action dated Februrary 27, 2003) are examined together because no undue burden for examining these claims together exists. If any questions remain regarding this Response, the Examiner is invited to contact the undersigned attorney at the phone number below.

Respectfully submitted,

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